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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/267,963	03/12/1999	KOHEI MIYAZONO	LUD-5539.1-C	7799

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EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/21/2002

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/267,963

Applicant(s)

MIYAZONO ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-53 is/are pending in the application.
- 4a) Of the above claim(s) 29-42, 50, 51 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-49, 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 29-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 29-53 are pending.

Applicant's election with traverse of group II, claims 43-52 to the extent that they are
5 drawn to a method for determining if a substance inhibits TGF- β /Alk-1 induced Smad1
phosphorylation, in Paper No. 20 is acknowledged. The traversal is on the ground(s) that all the
groups relate to the interaction of TGF- β and ALK-1 and all are classified the same. This is not
found persuasive because, considering the independent claims in each group, the methods are
independent and distinct, wherein each performs different functions, using different starting
10 materials, and can be practiced independently. Furthermore, the arts of Smad1 and Smad5
phosphorylation are not coextensive and require separate searches.

The requirement is still deemed proper and is therefore made FINAL.

Claims 29-42, 53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b),
15 as being drawn to a nonelected invention, there being no allowable generic or linking claim.
Applicant timely traversed the restriction (election) requirement in Paper No. 22. Since
Applicants elected group II, claims 43-52 to the extent that they are drawn to a method for
determining if a substance inhibits TGF- β /Alk-1 induced Smad1 phosphorylation, and since
claims 47, 50, 51 are directed to Smad5 phosphorylation, and since Applicants could have but did
20 not elect group III directed to Smad5 phosphorylation, claims 47, 50, 51 are withdrawn from
further consideration pursuant to 37 CFR 1.142(b), to the extent that they are drawn to a
nonelected invention, there being no allowable generic or linking claim.

Claims 43-49, 52 are being examined to the extent that they are drawn to a method for determining if a substance inhibits TGF- β /Alk-1 induced Smad1 phosphorylation.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-49, 52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification teaches that ALK-1 binds TGF- β 1 and Activin A in the presence of their respective type II receptors, but the functional consequences of the binding of the ligands remains to be elucidated (page 34, full paragraph 2). ALK-1 is a receptor for TGF- β (page 35, lines 19-20). Smad1 was phosphorylated following interaction with a constitutively active ALK-1 (page 36, lines 18-22). Leading the specification to assert that TGF- β binds to ALK-1 leading to phosphorylation of Smad1 (page 37, lines 26-27). However, there are no working examples demonstrating that TGF- β binds to ALK-1 leading to phosphorylation of Smad1. Although, the specification discloses that TGF- β binds Alk1, there is no indication that this binding effects or activates the receptor in any way. Binding does not equal activating. It would be reasonable to conclude that it would require undue experimentation to use the invention.

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Claim 52 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification teaches that Smad1 was phosphorylated following interaction with a

5 constitutively active ALK-1 (page 36, lines 18-22). In other words, in the presence of constitutively active ALK-1 phosphorylates Smad1 regardless of the presence or absence of TGF- β . In the presence of constitutively active ALK-1 either there is no TGF- β /Alk-1 induced Smad1 phosphorylation or the skilled artisan would be unable to distinguish TGF- β /Alk-1 induced Smad1 phosphorylation from constitutively active ALK-1 induced phosphorylation. Thus, there

10 would be no way to determine if a substance inhibits TGF- β /Alk-1 induced Smad1 phosphorylation in the presence of constitutively active Alk-1. There are no working examples of such a determination. It would be reasonable to conclude that it would require undue experimentation to use the invention.

15

Conclusion

No claims are allowed.

20 ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

25 IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL	(703) 872-9306
AFTER FINAL	(703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

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CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 20, 2002